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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,940	10/10/2000	Shi Kun Huang	5325-0166.30	6690

7590 10/01/2004

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/685,940

Applicant(s)

HUANG ET AL.

Examiner

Gollamudi S Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

RCE dated 6-13-04 is acknowledged.

Claims included in the prosecution are 1-18 and 30-33.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-15, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (5,965,434).

Wolff discloses liposomal compositions containing instant compounds where L is an ester and Z is either imidazole or an amino group. The liposomes carry either polypeptides or nucleic acids for transfection. The liposomes further include targeting ligand (note the abstract, structures on col. 6 and 7, compound 1 on col. 20, compounds 3 and 4 on columns 21 and 22, Examples 2-16 and claims).

According to instant independent claims, n can be either 0 or up to 20. When n=0, the imidazole (weakly basic group) is directly linked to 'L'; according to instant claims, L is selected from a Markush group wherein one of the members is a CH₂ group (iv in instant independent claims). In such a case, there will be 2 CH₂ groups in instant compound. When n is 1 or more in instant compounds, then the CH₂ groups are more

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than 2. In Wolff, 'n' is 1 and therefore, there is only one CH₂ group next to the imidazole moiety (weakly basic group); instant compounds therefore, are homologues of Wolff's compounds and it would have been obvious to one of ordinary skill in the art to prepare liposomes containing compounds where n is zero or more than one with an expectation of obtaining at least similar results, since homologues are expected to behave the same way.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Wolff's disclosure is a broad disclosure encompassing thousands of compounds. The examiner disagrees because the compounds 1 and 3 in Wolff are specific compounds and not compounds with a general formula as applicant is claiming through instant claims (which also incidentally encompass multitudes of compounds). The rejection is maintained.

3. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff cited above, further in view of Allen 96,056,973).

The teachings of Wolff have been discussed above. What are lacking in Wolff are the teachings of FGF as the targeting ligand.

Allen while disclosing liposomal compositions containing therapeutic agents, teaches that liposomes can be targeted to tumor cells by inclusion of targeting ligands such as FGF (note the abstract, col. 11, lines 45-53).

The inclusion of targeting ligand such as FGF in the liposomal compositions of Wolff would have been obvious to one of ordinary skill in the art since with such an inclusion, one could target tumor cells as taught by Allen.

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4. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff cited above, further in view of Zalipsky (5,395,619) of record.

Wolff does not teach the inclusion of a lipid derivatized with PEG.

Zalipsky while disclosing liposome formulations teaches that inclusion of a polymer-lipid conjugate will extend the circulation time of the liposome by several fold (note the abstract and col. 8, lines 45-53).

The inclusion of a polymer-lipid conjugate in the liposomes of Wolff would have been obvious to one of ordinary skill in the art since such an inclusion would extend the circulation time of the liposomes as taught by Zalipsky.

Applicant's arguments to the above two rejections have been fully considered, but are not found to be persuasive. The only argument put forth by applicant is that Allen or Zalipsky do not supply the missing information from Wolff. Since applicant's arguments regarding Wolff have already been addressed, the rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK